

Connecting The First And Last Mile Of Cell And Gene Therapy Delivery

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Becky Cap, Senior Vice President of Biotherapies at Vitalant, discusses how the merger addresses critical collection, processing, and logistics gaps to support the growing demand for cell and gene therapies across Southern California and beyond.



As cell and gene therapies advance toward broader commercial adoption, the industry faces mounting pressure to build the infrastructure required to support scalable and equitable patient access. The recent integration of Vitalant and San Diego Blood Bank reflects a growing recognition that collection, processing, logistics, and workforce readiness are becoming as important as therapeutic innovation itself. **In this interview, Becky Cap, Senior Vice President of Biotherapies at Vitalant,** shares how the merger is helping bridge critical infrastructure gaps, strengthen vein to vein delivery capabilities, and position blood centers as strategic partners in the future of cell and gene therapy delivery.

What were the strategic drivers behind the merger, particularly in the context of growing CGT demand in Southern California?

By leveraging combined expertise and resources, Vitalant and San Diego Blood Bank can offer integrated support, expanded reach, and advanced capabilities to donors, healthcare partners and patients alike. Further, there is a shared recognition that cell and gene therapies are scaling faster than the infrastructure needed to deliver them. Southern California is home to one of the densest biotech corridors in the world, yet the region's capacity for leukapheresis, cryopreservation, and GMP-compliant cell processing has not kept pace with the volume of clinical trials and newly licensed therapies entering the market.

San Diego Blood Bank brings deep community relationships and regional expertise. Vitalant brings a national footprint, about 115 donation centers, and decades of experience in HPC collection, HLA typing, and cell processing under FACT accreditation. Together, the organizations create a platform that connects Southern California's innovation ecosystem to a coast-to-coast delivery network.

Rather than building parallel infrastructure from scratch, we are extending and integrating what already works. The patients

who need these therapies cannot wait or afford for new systems to be invented. They need existing ones to be connected.

How critical is regional infrastructure expansion in addressing the operational complexity of vein-to-vein therapy delivery?

It is essential. Vein-to-vein delivery is not a single event. It is a chain of time-sensitive, regulated steps: donor or patient identification, leukapheresis collection, cold chain transport, manufacturing, quality release, and infusion. Each step involves different teams, different facilities, and often different organizations, all operating under strict timelines.

When that chain is concentrated in a handful of academic centers, geography becomes a barrier to care. Patients travel long distances, appointments are delayed, and the system bottlenecks at collection and processing. Regional expansion distributes the workload and brings services closer to the patient. In the current paradigm, 85% of otherwise qualified patients go without CAR-T therapy in part due to the lack of infrastructure in the patient's community.

Blood centers already operate this kind of distributed, time-sensitive network for blood products. We collect in communities, test, process, store, and deliver biological products every day under FDA oversight and cGMP conditions. Applying that operational model to CGT is not a conceptual leap. It is a natural extension of what we do.

What gaps currently exist in leukapheresis and cryopreservation capacity across the US CGT ecosystem?

The most significant gap is geographic. Leukapheresis and cryopreservation services are heavily concentrated in population dense regions with large academic medical centers and a small number of specialized facilities. Most community hospitals, where the majority of patients receive their care, do not have apheresis collection programs or GMP-compliant processing capabilities.

There is also a workforce gap. Trained apheresis nurses, cell processing technologists, and medical directors with experience in both transfusion medicine and biotherapies are in short supply. As the number of approved CGT products grows and clinical trials multiply, the demand for qualified personnel will outpace availability unless we invest in training and create career pathways that attract talent into this space.

Finally, there is a coordination gap. Collection, processing, and manufacturing often involve different organizations with different quality systems and data platforms. Standardizing handoffs across these boundaries is one of the most practical challenges the field faces today in connecting the first and last mile of therapy. Vitalant is known for helping in this coordination gap already and San Diego Blood Bank will only strengthen this ability.

How do you see blood centers evolving beyond traditional collection roles into integrated therapy enablement partners?

This evolution is already underway. Blood centers have always been more than collection organizations. We operate regulated laboratories, manage complex donor registries, maintain cold chain logistics networks, and ensure the safety and traceability of biological products from donor to patient. We are implementing a hub and spoke model for collections that will allow our nurses to support patient's needs in a wide variety of community settings under a unified operational, medical, and quality/regulatory leadership.

What is changing is the scope of the products and the complexity of the clinical relationships. We are now collecting cellular starting materials for CAR-T manufacturing, performing HLA typing for donor-patient matching, cryopreserving HPC products, and supporting hospitals that lack the internal capacity to participate in clinical trials.

The shift is from just a supplier to a clinical partner in a therapeutic workflow. That requires investment in quality systems, workforce development, FACT accreditation, and the ability to work within the regulatory frameworks governing investigational products. Vitalant has made those investments because we believe patient access depends on it.

What operational lessons from the blood sector can CGT developers adopt to improve scalability and patient access?

Three lessons stand out.

First, standardize where you can and customize only where you must. The blood services sector learned long ago that consistency in collection, processing, and distribution is what enables scale. CGT developers often design bespoke

workflows for every product and every site. That approach works in early-phase trials but is often not scalable.

Second, plan for the last mile. Manufacturing a therapy is only part of the equation. Getting the right product to the right patient at the right time, in the right condition, with full chain of custody, is where many programs fail. Blood centers are adept at doing this every day.

Third, invest in people and infrastructure before demand arrives. The blood services sector did not wait for a crisis to build donor centers and train phlebotomists. CGT developers and health systems that wait until capacity is a bottleneck will find themselves competing for the same scarce resources. The time to build is now.